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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY NEWARK DIVISION

Case No: 2:20-cv-08030-SDW-LDW

RUTH LARA, Individually and as Guardian of her minor child J.S., on behalf of themselves and on behalf of those similarly situated,

CLASS ACTION COMPLAINT CLASS REPRESENTATION

Plaintiffs,

DEMAND FOR JURY TRIAL

v.

PUFF BAR, NICK MINAS,
PATRICK BELTRAN, COOL CLOUDS
DISTRIBUTION, INC.,
UMAIS ABUBAKER,
and SHAHID SHAIKH,

Defendants.			

SECOND AMENDED CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

1. Plaintiffs, Ruth Lara, individually, and as legal Guardian of her minor child, J.S., by and through undersigned counsel, bring this action against Defendants, Puff Bar, Nick Minas, Patrick Beltran, Cool Clouds Distribution, Inc., Umais Abubaker, and Shahid Shaikh, on behalf of themselves and those similarly situated, and allege as follows:

INTRODUCTION

- 2. The United States faces a youth nicotine epidemic. The result—a generation of addicted youth—has been devastating. The tobacco control and public health organizations recognize that prior progress lowering youth nicotine usage is eroding.
- 3. In an effort to address the epidemic, the FDA recently issued a ban on flavored ecigarette pods and cartridges except for those that are menthol and tobacco flavored.¹
- 4. Despite legislation banning fruit, mint, and dessert flavors in refillable cartridge-based e-cigarettes, the ban carved out an exemption for brands that are used once and thrown away. Puff Bar, a disposable e-cigarette that launched in 2019, has been the key beneficiary of the loophole. Puff bar is sleek, appealing, concealable, and exceptionally easy to use. Puff Bar is designed to deliver nicotine more efficiently than some earlier brands. Available in 25 different flavors this e-cigarette is made for youth. The company built on its early success by adding a line of flavor pods called "Puff Krush," which are compatible with other e-cigarettes and further target the youth market.
- 5. Even though e-cigarettes are unsafe for anyone under 26, Puff Bar heavily promotes and markets these products to young people. Puff Bar preys on youth using themes that exploit young users' vulnerabilities to create and sustain nicotine addiction, all for financial gain, and without giving users any warnings about the serious risks of addiction and other serious injuries.
- 6. Plaintiff, J.S., was a target and victim of Puff Bar's conduct. As a result of Puff Bar's conduct Plaintiffs, and those similarly situated, have been injured and seek redress.

PARTIES, JURISDICTION, AND VENUE

¹ Allison Aubrey, *Trump Administration Issues Partial and Temporary E-Cigarette Ban*, NPR: NATIONAL (Jan 2, 2020), https://www.npr.org/2020/01/02/793134344/trump-administration-issues-partial-and-temporary-e-cigarette-ban#:~:text=The%20Trump%20administration%20announced%20a,of%20tobacco%20and%20menthol%20flavors.

- 7. Plaintiff, Ruth Lara, is the parent and natural guardian of J.S. Plaintiffs reside in Morris County, New Jersey, and are citizens of the State of New Jersey. J.S., is only 17 years old. J.S. began using Puff Bar products in early 2019, when first released on the market, as a direct result of the numerous kid-friendly flavors offered by Puff Bar.
 - 8. Plaintiff, J.S., smokes Puff Bar products, including Puff Bar Plus.
 - 9. Plaintiff, J.S., has seen Puff Bar advertisements.
- 10. Plaintiff, J.S., purchased Puff Bar products from retail stores in the State of New Jersey.
- 11. Plaintiff, J.S., did not know how much nicotine Puff Bar contained or that Puff Bar was specifically developed to create and sustain a nicotine addiction when he began using it. Plaintiff, J.S. did not know that one Puff Bar contains more nicotine than a pack of cigarettes. He now suffers from nicotine addiction and other physical and personal injuries. Plaintiff was directly and proximately harmed by Defendants' unlawful conduct as alleged herein. Such harms include physical and personal injuries and economic harm in that he would not have purchased Puff Bar and Puff Bar products if he knew the facts.
- 12. Defendant, Puff Bar, is a California corporation, having its principal place of business in Glendale, California. Puff Bar manufactures, designs, sells, markets, promotes and distributes Puff Bar disposable e-cigarettes, Puff Krush flavored tip add-ons, and other Puff Bar products throughout the United States. Puff Bar purposefully marketed and sold its products to the citizens of the State of New Jersey.
- 13. Defendant, Nick Minas, is the Chief Executive Officer of Puff Bar and is a citizen of the State of California. Mr. Minas is involved in designing, manufacturing, promoting and selling Puff Bar disposable e-cigarettes, Puff Krush flavored tip add-ons, and other Puff Bar

products throughout the United States. Nick Minas had control over the company as Chief Executive Officer, was involved in the marketing and sale of Puff Bar products, and those products are purposefully sold throughout the United States, including the State of New Jersey. Because this conduct was designed to, and did, impact purchasers in New Jersey, Mr. Minas is subject to specific jurisdiction in the New Jersey courts.

- 14. Defendant, Patrick Beltran, is the Chief Financial Officer of Puff Bar and is a citizen of the State of California. Mr. Beltran is involved in designing, manufacturing, promoting and selling Puff Bar disposable e-cigarettes, Puff Krush flavored tip add-ons, and other Puff Bar products throughout the United States. Patrick Beltran had control over the company as Chief Financial Officer, was involved in the marketing and sale of Puff Bar products, and those products are purposefully sold throughout the United States, including the State of New Jersey. Because this conduct was designed to, and did, impact purchasers in New Jersey, Mr. Beltran is subject to specific jurisdiction in the New Jersey courts.
- 15. Defendant, Cool Clouds Distribution, Inc. ("Cool Clouds"), is a California corporation, having its principal place of business in Los Angeles, California. Cool Clouds manufactures, designs, sells, markets, promotes and distributes Puff Bar disposable e-cigarettes, Puff Krush flavored tip add-ons and other Puff Bar products throughout the United States. Cool Clouds purposefully marketed and sold its products to the citizens of the State of New Jersey.
- 16. Defendant, Umais Abubaker, is the Chief Executive Officer of Cool Clouds and is a citizen of the State of California. Mr. Abubaker is, upon information and belief, involved in designing, manufacturing, promoting and selling Puff Bar, Puff Krush and other Puff Bar products throughout the United States. Mr. Abubaker had control over the company as Chief Executive Officer, was involved in the marketing and sale of Puff Bar products, and those products are

purposefully sold throughout the United States, including the State of New Jersey. Because this conduct was designed to, and did, impact purchasers in New Jersey, Mr. Abubaker is subject to specific jurisdiction in the New Jersey courts.

- 17. Defendant, Shahid Shaikh, is the Chief Operating Officer of Cool Clouds and is a citizen of the State of California. Mr. Shaikh is, upon information and belief, involved in designing, manufacturing, promoting and selling Puff Bar, Puff Krush and other Puff Bar products throughout the United States. Mr. Shaikh had control over the company as Chief Executive Officer, was involved in the marketing and sale of Puff Bar products, and those products are purposefully sold throughout the United States, including the State of New Jersey. Because this conduct was designed to, and did, impact purchasers in New Jersey, Mr. Shaikh is subject to specific jurisdiction in the New Jersey courts.
- 18. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because: (i) there are 100 or more class members; (ii) the aggregate amount in controversy exceeds \$5,000,000, exclusive of interest and costs; and (iii) at least one Plaintiff and Defendant are citizens of different states. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.
- 19. The Court has personal jurisdiction over all Defendants because they have sufficient minimum contacts with Morris County, New Jersey. Defendants intentionally avail themselves of the markets in this State through the promotion, marketing, distribution or sale of the products at issue in this lawsuit to render the exercise of jurisdiction by this Court permissible under New Jersey law and the U.S. Constitution.
- 20. Venue is proper in the District of New Jersey pursuant to 28 U.S.C. § 1391 (b)(2) and (3) because a substantial part of the events or omissions giving rise to the claims at issue in this

Complaint arose in this District and Defendants are subject to the Court's personal jurisdiction with respect to this action.

GENERAL FACTUAL ALLEGATIONS

A. The E-Cigarette Epidemic.

- 21. According to the CDC, about 4.9 million middle and high school students were current users of a tobacco product in 2018, meaning that they used such products within the past 30 days. This represents an increase of 1.3 million users just since 2017.²
- 22. A surge in e-cigarette use explains this dramatic increase. E-cigarette use among U.S. high school students increased more than 900% from 2011 to 2015.
- 23. The 2018 National Youth Tobacco Survey "finds cause for concern." Specifically, the FDA found that the increase in youth tobacco usage stood to erase past progress in reducing youth tobacco product use. *See id.* Frequent use of e-cigarettes increased from 20% in 2017 to 28 percent in 2018. *Id.* E-cigarette use in general increased 78% among high school students and 48% among middle school students from 2017 to 2018. *Id.*
- 24. The 2019 National Youth Tobacco Survey "shows youth e-cigarette use at *alarming levels*." This time, the FDA found that there 1.4 million more youth e-cigarette users in 2019 than in 2018, for a startling total of over 5 million youths using e-cigarettes. *Id*.

² Progress Erased: Youth Tobacco Use Increased During 2017–2018, CDC, https://www.cdc.gov/media/releases/2019/p0211-youth-tobacco-use-increased.html (last updated Feb. 11, 2019).

³ Results from 2018 National Youth Tobacco Survey Show Dramatic Increase in E-Cigarette Use Among Youth Over Past Year, FDA, https://www.fda.gov/news-events/press-announcements/results-2018-national-youth-tobacco-survey-show-dramatic-increase-e-cigarette-use-among-youth-over (last updated Nov. 15, 2018).

⁴ Youth Tobacco Use: Results from the National Youth Tobacco Survey, FDA, https://www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey (last updated Nov. 6, 2019).

- 25. As CDC Director Dr. Robert R. Redfield explains: "The skyrocketing growth of young people's e-cigarette use over the past year threatens to erase progress made reducing tobacco use. It's putting a new generation at risk for nicotine addiction." *Id*.
- 26. Many youth tobacco product users are also using multiple tobacco products: a combination of e-cigarettes and conventional cigarettes.
- 27. The FDA characterizes teen vaping as an epidemic. And with good reason: Smoking is the leading cause of preventable death. Cigarette smoking causes about one in every five deaths in the United States each year. This amounts to around 480,000 deaths annually. If smoking continues at the current rate among U.S. youth, 5.6 million of today's Americans younger than 18 years of age are expected to die prematurely from a smoking-related illness. This represents about one in every 13 Americans aged 17 years or younger who are alive today.
- 28. A study done by the American Journal of Medicine found that among young adults who did not smoke cigarettes, those who used e-cigarettes were more than four times as likely than non-vapers to start smoking traditional cigarettes within 18 months.⁵
- 29. The vaping epidemic has swept the entire nation in a short period of time. On December 28, 2018, the University of Michigan's National Adolescent Drug Trends for 2018 reported that increases in adolescent Electronic Nicotine Delivery System ("ENDS") vaping from 2017 to 2018 were the "largest ever recorded in the past 43 years for any adolescent substance use outcome in the U.S."
- 30. The percentage of 12th grade students who reported vaping nicotine almost doubled between 2017 and 2018, rising from 11% to 21%. The ten-percentage-point increase in 12th grade

⁵ Primack, Brian A. MD, PhD. *Initiation of Traditional Cigarette Smoking after Electronic Cigarette Use Among Tobacco-Naïve US Young Adults*, Am. J. OF MEDICINE (Nov. 2017).

⁶ Prieur, *National Adolescent Drug Trends in 2018* (Dec. 17, 2018), UNIV. OF MICHIGAN, https://isr.umich.edu/news-events/news-releases/national-adolescent-drug-trends-in-2018/ (as of Oct. 5, 2019).

students who reported vaping nicotine (an indicator of nicotine addiction) is "twice as large as the previous record for largest-ever increase among past 30-day outcomes in 12th grade." *Id.* "One in five 12th graders vaped nicotine in the last 30 days in 2018." *Id.*

- 31. Former FDA Commissioner, Dr. Scott Gottlieb, has described the increase in e-cigarette consumption as an "almost ubiquitous—and dangerous—trend" that is responsible for an "epidemic" of nicotine use among teenagers. The rapid, and indeed infectious, adoption of e-cigarettes "reverse[s] years of favorable trends in our nation's fight to prevent youth addiction to tobacco products." Id. (emphasis added). The Commissioner identified the two primary forces driving the epidemic as "youth appeal and youth access to flavored tobacco products." Id.
- 32. Within days of the FDA's declaration of an epidemic, Surgeon General Dr. Jerome Adams also warned that the "epidemic of youth e-cigarette use" could condemn a generation to "a lifetime of nicotine addiction and associated health risks."

B. Puff Bar, A Salt-Nicotine Delivery Device, Is Unreasonably Dangerous.

- 33. The Puff Bar e-cigarette is a disposable pod device. The device is wholly self-integrated and features an internal battery and flavor pod. The battery uses auto-activation and has a buttonless design. Users need only start vaping to activate the device. The e-cigarette has no removable parts. There is no pod to remove, and there is no charging port to recharge the battery.
- 34. Puff Bar is remarkably easy-to-use. Users take out the device, and it is ready to vape. The battery is air-activated, so users need to pull on the mouthpiece to start the vaping process. There are air intake vents on the base, which is what pushes the vapor out from the mouthpiece.

8

⁷ Surgeon General's Advisory on E-cigarette Use Among Youth, CDC, www.cdc.gov/tobacco/basic_information/e-cigarettes/surgeon-general-advisory/index.html (last updated Apr. 9, 2019).

- 35. Puff Bar is small enough to fit in a pocket, resembles a USB flash drive, and heats up a cartridge containing e-liquid to create a vapor.
- 36. Each Puff Bar uses nicotine salts—a formula that allows for much higher levels and efficient delivery of nicotine with less irritation compared to earlier generations of e-cigarettes. Nicotine strength can be as high as 5% in Puff Bars.
- 37. Puff Bars are optimized to initiate and sustain nicotine addiction in America's youth. Puff Bar comes in a variety of kid-friendly flavors: Sour Apple, Cool Mint, Blue Razz, Pink Lemonade, to name a few. Similar to the way tobacco companies have long marketed flavored products to appeal to youth, Puff Bars emphasize flavors with bright-colored packaging and use descriptive names.
- 38. Defendants engineered an e-cigarette device capable of delivering more nicotine and fueling higher levels of consumer addiction than most prior versions of e-cigarettes and combustible cigarettes. Defendants market this highly addictive device as healthy, safe, cool and available in kid-friendly flavors.
- 39. Previously, most e-cigarettes used an alkaline form of nicotine called free-base nicotine. When aerosolized and inhaled, free-base nicotine is relatively bitter, irritates the throat, and is perceived as harsh by the user. This experience is often referred to as a "throat hit." The higher the concentration of free-base nicotine, the more intense the "throat hit." While some "harshness" would not have much impact on seasoned cigarette smokers, it would deter newcomers, or nicotine "learners," as Claude Teague at R.J. Reynolds called young non-smokers decades ago.

9

⁸ Robert K. Jackler & Divya Ramamurthi, *Nicotine Arms Race: JUUL and the High-Nicotine Product Market*, 28 TOBACCO CONTROL 623 (2019).

- 40. Before 2015, most e-liquids on the market were between 1% and 2% concentration; 3% concentrations were marketed as appropriate for consumers who were accustomed to smoking approximately forty cigarettes a day. None of these e-liquids delivered as much nicotine as quickly as a combustible cigarette.
- 41. E-cigarette manufacturers like Puff Bar learned, however, that a nicotine salt formulation would maximize buzz and minimize harshness.
- 42. Dramatically reducing the throat hit is not necessary for a product that is aimed at smokers, who are accustomed to the harshness of cigarette smoke, but it effectively appeals to nonsmokers, especially youth. The cigarette industry has long recognized this; a published study of industry documents concluded that "product design changes which make cigarettes more palatable, easier to smoke, or more addictive are also likely to encourage greater uptake of smoking."
- 43. Reducing the harshness of nicotine also allows more frequent use of e-cigarettes like Puff Bar, for longer periods of time, and masks the amount of nicotine being delivered. By removing the physiological drawbacks of inhaling traditional free-base nicotine, Puff Bar's e-cigarette technology removes the principal barrier to nicotine consumption and addiction.
- 44. In other words, Puff Bar works all too efficiently, and is therefore unreasonably dangerous, delivers nicotine, both in terms of peak blood concentration and total nicotine delivery. The rate of nicotine absorption is key to providing users with the nicotine "kick" that drives addiction and abuse. Because "nicotine yield is strongly correlated with tobacco consumption," 10

⁹ David A. Kessler, *Juul Says It Doesn't Target Kids. But Its E-Cigarettes Pull Them In*, N.Y. TIMES (July 31, 2019), https://www.nytimes.com/2019/07/31/opinion/juul-kids.html.

Martin J. Jarvis et al., Nicotine Yield From Machine Smoked Cigarettes and Nicotine Intakes in Smokers: Evidence From a Representative Population Survey, 93 NAT'L CANCER INST. 134 (Jan. 17, 2001), https://academic.oup.com/jnci/article/93/2/134/2906355.

a nicotine-salt-based e-cigarette will strongly correlate with higher nicotine levels and therefore higher rates of consumption. For example, a historic cigarette industry study that looked at smoker employees found that "the number of cigarettes the employees smoked per day was directly correlated to the nicotine levels." In essence, Puff Bar's potency centers on its e-liquids' extraordinary potential to addict.

C. Puff Bar Is Specifically Designed to Circumvent the FDA's Partial Flavor Ban.

- 45. Puff Bar comes in 25 different flavors, and the Puff Krush flavored tip which can be added on to vaping devices and also comes in various fruity flavors, such as Sour Apple, O.M.G. (Orange, Mango, Guava), Cool Mint, Cucumber, Mango, Watermelon, Caffe Latte, Strawberry, Lush Ice, Blue Razz, Pink Lemonade, Pineapple Lemonade, Banana Ice, Strawberry Banana.
- 46. There is concern that youth are migrating to Puff Bar's fruity-flavored disposable products while most other flavored pod-based vapes have been removed from store shelves. This severely undercuts the purpose of the FDA's partial flavor ban.
- 47. There is additional concern that Puff Krush is "a new tobacco product specifically designed to circumvent [the] FDA's partial flavor ban. Puff Krush can be added onto other vaping devices, converting them into flavored products. The Puff Krush packaging shows the device being inserted onto an image of a JUUL device, and [Puff Krush] markets them as produced to function with nicotine sale devices."¹²

¹¹ Letter from Peggy Martin to Study Participants, *Resume of Results from Eight-Week Smoking Study*, UCSF LiB., 1003285443-5443 (Sept. 10, 1971).

¹² Letter from Chairman Raja Krishnamoorthi to Puff Bar CEO, Umais Abubaker, Congress of the United States, Committee on Oversight and Reform (Mar. 6, 2020), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-03-06.RK%20to%20Abubaker%20Cool%20Cloud%20Distributions%20re%20Puff%20Bars%20Disposable%20Offerings.pdf.



- 48. In light of Puff Bar's May 2019 date of incorporation and January 2020 registration for trademark protection, Congressman Raja Krishnamoorthi, Chairman of the Oversight Subcommittee on Economic and Consumer Policy, concluded Puff Bar is either "selling a new tobacco product or [is] looking to expand [its] sales in the wake of the disposable e-cigarette loophole that [the] FDA included in its flavor guidance. *Id*.
- 49. After August 8, 2016, the FDA required that all new e-cigarette manufacturers receive premarket approval before selling their products.
- 50. Christin Delnevo, director of the Center for Tobacco Studies at Rutgers University, said, "[w]hen we saw these products, we went to the FDA site to see which products had been given market authorization. We could not find any of these disposable 'pod mods' listed there." ¹³
- 51. "Without the marketing authorization, these products are on the market illegally." *Id.*

¹³ Puff, Puff, Pass: A New Vape with Hazy Origins Takes JUUL's Place, INVERSE, https://www.inverse.com/mind-body/puffbar-flavor-vapes (last visited June 16, 2020).

- 52. Moreover, Puff Bar represents that its product is safer than cigarettes. For example, in an official blog post on Puff Bar's website, the company stated, "Puff Bar was founded with three core values in mind: simplicity, value, and offering a healthier alternative to cigarettes." Puff Bar, however, has not obtained FDA approval to make a modified risk claim.
- 53. Puff Bar is also portraying without any support or authorization from the FDA that its product is a smoking cessation device. It's website stated: "The most important thing Puff Bar aims to do is help people quit smoking cigarettes." Puff Bar, however, has not obtained FDA approval to make such a claim as well.

D. Puff Bar Is Currently on the Market Illegally.

- 54. Puff Bar Came onto the United States market in 2019—well after the FDA's Deeming Rule, which finalized a rule regulating all tobacco products including e-cigarettes, took effect on August 8, 2016.
- 55. The Deeming Rule prohibited "new tobacco products" from being introduced without first undergoing premarket review and receiving marketing authorization.¹⁴
- 56. On June 20, 2019, the FDA Office of Compliance and Enforcement Center for Tobacco Products sent a notice to Nick Minas (Puff Bar CEO) and Patrick Beltran (Puff Bar CFO), acting on complaints that the company commercially marketed Puff Pods in the United States illegally after the Deeming Rule took effect in 2016.¹⁵

¹⁴ Final Rule, Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, *as amended by* the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28, 974 (May 10, 2016).

¹⁵ Ann Simoneau, J.D., Director Office of Compliance and Enforcement, CTR. FOR TOBACCO PRODS. (June 20, 2019), www.fda.gov/media/128982/download.

E. Puff Bar Targets the Youth Market.

- 1. Puff Bar Emulates the Marketing of Cigarette Companies.
- 57. Nearly 9 out of 10 smokers start smoking by age 18, and more than 80% of underage smokers choose brands from among the top three most heavily advertised.¹⁶
- 58. For decades, cigarette companies spun smoking as signifier of adulthood. This turned smoking into a way for teenagers to project independence and enhance their image among their peers.¹⁷
- 59. Youth marketing was critical to the success of cigarette companies. In the 1950s, Philip Morris USA, Inc., for example, intentionally marketed cigarettes to young people as a pool from which to "replace smokers" to ensure the economic future of the cigarette industry. *Id.*
- 60. An internal memorandum dated March 31, 1981 sent by Myron Johnston, a marketing researcher for Philip Morris, states: "It is important to know as much as possible about teenage smoking patterns and attitudes. Today's teenager is tomorrow's potential regular customer, and the overwhelming majority of smokers first begin to smoke while still in their teens." ¹⁸
- 61. To accomplish this sordid goal, Philip Morris tracked youth behavior and preference; employed marketing themes that resonated with youth; and promoted cigarettes to youth through retail promotions, events and sponsorships.
- 62. Philip Morris intentionally exploited adolescents' vulnerability to imagery by creating advertising that utilizes the themes of independence, adventurousness, sophistication,

¹⁶ Preventing Tobacco Use Among Youths, Surgeon General Fact Sheet, https://www.hhs.gov/surgeongeneral/reports-and-publications/tobacco/preventing-youthtobacco-use-factsheet/index.html (last visited Dec. 9, 2019).

¹⁷ USA v. Philip Morris, 449 F. Supp. 2d 1, 1072 (D.D.C. 2006) (J. Kessler).

¹⁸ Tobacco Company Quotes on Marketing to Kids, Campaign for Tobacco-Free Kids (May 14, 2001), https://www.tobaccofreekids.org/assets/factsheets/0114.pdf.

glamour, athleticism, social inclusion, sexual attractiveness, thinness, popularity, rebelliousness, and being "cool." Philip Morris' marketing tactics consistently reached millions of teens.

- 63. It wasn't just Philip Morris. The strategy of hooking kids was an open secret in the cigarette industry. The cigarette industry has long known that the younger a person starts smoking, the longer they will have a customer.
- 64. Historically, cigarette companies fought to increase share penetration among the 14–24 age group because "young smokers have been the critical factor in the growth" of tobacco companies, and "the 14–18 year old group is an increasing segment of the smoking population." The importance of the youth market was illustrated in a 1974 presentation by R.J. Reynold's Vice-President of Marketing who explained that the "young adult market . . . represent[s] tomorrow's cigarette business. As this 14 24 age group matures, they will account for a key share of the total cigarette volume—for at least the next 25 years."
- 65. The landmark *USA v. Philip Morris*, 449 F. Supp. 2d 1 (D. D.C. 2006) case revealed that tobacco companies targeted adolescents for decades by: "(1) employ[ing] the concept of peers in order to market to teenagers; (2) us[ing] images and themes in their marketing that appeal to teenagers; and (3) employ[ing] advertising and promotion strategies to knowingly reach teenagers." In terms of images and themes that cater to adolescents, the court found "overwhelming" evidence that tobacco companies intentionally exploited adolescents' vulnerability to imagery by creating advertising emphasizing themes of "independence,

Memo to: C.A. Tucker from: J.F. Hind Re: "Meet the Turk" (January 23, 1978) http://legacy.library.ucsf.edu/tid/lve76b00 (as of Oct. 15, 2018).

Mr. C.A. Tucker Presentation to RJRI BOfD - 9/30/74 (740930), "Marketing Plan" (1974), www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=ypmw0091 (as of Oct. 5, 2019).

adventurousness, sophistication, glamour, athleticism, social inclusion, sexual attractiveness, thinness, popularity, rebelliousness, and being 'cool.'" *Id.* at ¶ 2674.

- 66. Cigarette companies have also known for decades that flavored products are key to nicotine adoption by youth. A 1972 Brown & Williamson internal memorandum titled "Youth Cigarette—New Concepts," observed that "it's a well-known fact that teenagers like sweet products." A 1979 Lorillard memorandum found "younger" customers would be "attracted to products with 'less tobacco taste," and suggested investigating the "possibility of borrowing switching study data from the company which produces 'Life Savers' as a basis for determining which flavors enjoy the widest appeal" among youth. A 2008 study found that 17-year-old smokers were more than three times as likely as those over the age of 25 to smoke flavored cigarettes, and they viewed flavored cigarettes as safer. Cigarette companies also used advertisements that paired cigarettes with foods, to make it seem like cigarettes were part of a healthy meal.
- 67. Puff Bar has emulated this approach. It has deployed this same strategy but adapted it to modern advertising tactics.

2. Puff Bar Intentionally Markets to Youth.

68. Like tobacco marketing, Puff Bar runs a consistent, simple message: Puff Bar is used by young, popular, attractive, and stylish people. Puff Bar uses stylish models, bold colors,

²¹ Brown & Williamson official A.J. Mellman, (1983) *Tobacco Industry Quotes on Nicotine Addiction*, www.ok.gov/okswat/documents/Tobacco%20Industry%20Quotes %20on%20Nicotine%20Addiction.pdf (as of Oct. 15, 2019).

²² Flavored Tobacco FAQs, Students Working Against Tobacco, (citing, Sedgefield Idea Sessions 790606-790607. June 8, 1979. Bates No. 81513681/3691),

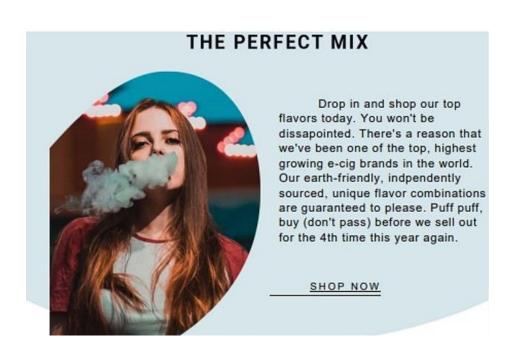
 $http://swatflorida.com/uploads/fightresource/Flavored\%\,20 Tobacco\%\,20 Industry\%\,20 Quotes\%\,20 and\%\,20 Facts.pdf (as of Oct.\,15,\,2019).$

²³ Klein *et al.*, *Use of flavored cigarettes among older adolescent and adult smokers: United States*, 2004–2005. (July 2008) Nicotine Tob Res. 10(7):1209-14, https://www.ncbi.nlm.nih.gov/pubmed/18629731 (as of Oct. 15, 2019).

and highlighted themes of sexual attractiveness, thinness, independence, rebelliousness and being "cool."

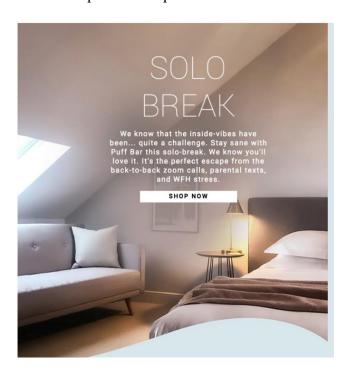
69. The collection of fruit flavors epitomizes health and is hardly suggestive of addiction and health harm.





70. Puff Bar is also exploiting the COVID-19 crisis by using it as a marketing tactic.

71. For example, in April 2020, Puff Bar urged kids to "stay sane with Puff Bar this solo-break" since it's the "perfect escape from the back-to-back zoom calls" and "parental texts":



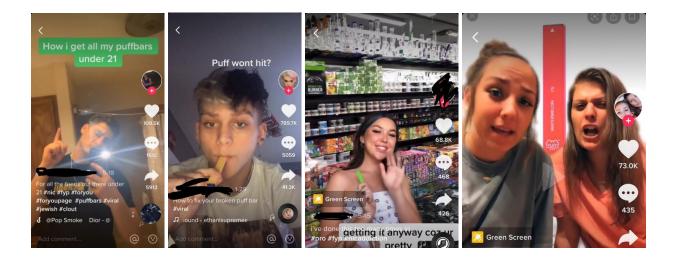
- 72. There can be no doubt that these advertisements are targeting minors and/or are likely to promote their use by minors. After all, how many adults need to take break from "parental texts?"
- 73. Puff Bar's website states: "Think of it as a cheaper, more convenient alternative to smoking a cigarette . . . The device itself is slim, sleek, and designed to stay out of your way. It's made to complement your lifestyle, not constrain it."²⁴
- 74. Puff Bar is also featured on the major social media sites used by adolescents, including YouTube, TikTok, Instagram, and Reddit.
- 75. Puff Bar product reviews and 'how-to' videos on YouTube have gained high numbers of viewers, including youth under the age of 18. As an example, a screenshot from

https://puffbar.com/blogs/vape-news/puff-bar-101-everything-you-ever-wanted-to-know-about-the-puff-bar-disposable-device.

ChaseSmokers shows over 100,000 views (on 7/26/20) and hundreds of viewer comments, including youth under the age of 18.



76. Screenshots of examples of TikTok videos promoting Puff Bars with young followers, views exceeding one million, and the numbers of likes as high as 789.7K.



77. There are multiple Puff Bar accounts on Instagram (owned by Nick Minas and Patrick Beltran), one of which has 22.3K followers. The Instgram hashtag #puffbar has over 34.5K posts.

F. Puff Bar Use Increases the Risk of Cardiovascular, Pulmonary, Neurological, and Other Bodily Injuries.

- 1. The Dangers of Nicotine.
- 78. Aside from being a toxicant, the impact of nicotine on adolescents' developing brains is extremely concerning.
- 79. Adolescence is a critical window for brain development, with the brain not reaching full maturity until the mid-20s. Vaping in adolescence exposes the developing brain to nicotine with the potential to cultivate addiction and drive sustained long-term use.²⁵ As a consequence, adolescents are highly vulnerable to addiction to nicotine. The effects of nicotine on the brain are believed to be long-lasting and likely permanent.
- 80. Adolescents using vaping devices that contain nicotine are developing dependence to the products. Experts specializing in nicotine addiction have studied the correlation between vaping and dependence in adolescents and found that the level of e-cigarette addiction correlates significantly with their level of nicotine exposure.²⁶
- 81. Nicotine is an alkaloid, a class of plant-derived nitrogenous compounds that is highly addictive and the key ingredient that drives addiction to cigarettes. Nicotine's addictive properties are like heroin and cocaine.²⁷
- 82. The route of administration and speed of delivery are key to understanding nicotine's addictive potential. According to the National Institutes of Health, the "amount and speed of nicotine delivery . . . plays a critical role in the potential for abuse of tobacco products." 28

²⁵ England LJ, Aagaard K, Bloch M, et al., *Developmental Toxicity of Nicotine: A Transdisciplinary Synthesis and Implications for Emerging Tobacco Products*, NEUROSCIENCE & BEHAVIORAL REVIEWS (2017).

²⁶ Vogel EA, Prochaska JJ, Rubinstein M., *Measuring E-Cigarette Addiction Among Adolescents*, TOBACCO CONTROL, https://tobaccocontrol.bmj.com/content/early/2019/05/10/tobaccocontrol-2018-054900.full.

²⁷ See Nicotine Addiction: A Report of the Surgeon General, DHHS Publication Number (CDC) 88-8406, (1988).

²⁸ How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General, NIH (2010), https://www.ncbi.nlm.nih.gov/books/NBK53018/#ch4.s92.

- 83. Dr. Neal Benowitz, Scientific Editor of the 1988 Surgeon General's Report on nicotine addiction, wrote: "After a puff, high levels of nicotine reach the brain in 10–20 s[econds], faster than with intravenous administration, producing rapid behavioral reinforcement. The rapidity of rise in nicotine levels permits the smoker to titrate the level of nicotine and related effects during smoking, and makes smoking the most reinforcing and dependence-producing form of nicotine administration."²⁹
- 84. Again, according to Dr. Benowitz, "The rapid rate of delivery of nicotine by smoking . . . results in high levels of nicotine in the central nervous system with little time for development of tolerance. The result is a more intense pharmacologic action. The short-time interval between puffing and nicotine entering the brain also allows the smoker to titrate the dose of nicotine to a desired pharmacologic effect [often subconsciously], further reinforcing drug self-administration and facilitating the development of addiction." *Id*.
- Nicotine fosters addiction through the brain's "reward" pathway. Both a stimulant and a relaxant, nicotine affects the central nervous system; increases blood pressure, pulse, and metabolic rate; constricts blood vessels of the heart and skin; and causes muscle relaxation. Long-term exposure to nicotine causes upregulation—an increase in the number of these high-affinity nicotinic receptors in the brain. When nicotine binds to these receptors it triggers a series of physiological effects in the user that are perceived as a "buzz" that includes pleasure, happiness, arousal, and relaxation of stress and anxiety. With regular nicotine use, however, these feelings diminish, and the user must consume increasing amounts of nicotine to achieve the same effects.

²⁹ Neal L. Benowitz et al., *Nicotine Chemistry, Metabolism, Kinetics and Biomarkers*, 192 HANDB. EXP. PHARMACOL., 29 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2953858/.

- 86. Kids are particularly vulnerable to nicotine addiction. As described by the United States Surgeon General, "Tobacco use is a pediatric epidemic." Nine out of ten smokers begin by age 18 and 80% who begin as teens will smoke into adulthood.³⁰
- 87. In 2014, the United States Surgeon General reported that nicotine addiction is the "fundamental reason" that individuals persist in using tobacco products, and this persistent tobacco use contributes to millions of needless deaths and many diseases, including diseases that affect the heart and blood vessels (cardiovascular disease), lung diseases (chronic obstructive pulmonary disease ("COPD") and lung cancer), cancer almost anywhere in the body, and birth defects.
- 88. Nicotine adversely affects the heart, eyes, reproductive system, lungs, and kidneys. Exposure to nicotine from sources such as nicotine gum still produces an increased risk of Coronary Vascular Disease by producing acute myocardial ischemia, as well as an increased risk of peripheral arterial disorders. Moreover, because vaping introduces foreign substances into the lungs, prolonged use of vaping products is believed to produce chronic obstructive pulmonary disease, just like traditional cigarette smoke. Vaping also triggers immune responses associated with inflammatory lung diseases.
- 89. The APA has also stated that nicotine-dependent smokers are up to 8 times more likely to develop psychotic disorders, depressive disorders, anxiety and delirium than smokers who are not dependent or those who have never smoked. Small scale studies have also found a relationship between high stress or depression and e-cigarette use.³¹
- 90. Beyond physical and psychological health harms, e-cigarette use propels adolescents towards other harmful behaviors, especially co-use and/or future use of combustible

³⁰ Preventing Tobacco Use Among Youth and Adults: A Report of the Surgeon General, at 1 (2012), https://www.hhs.gov/surgeongeneral/reports-and-publications/tobacco/index.html.

³¹ King JL, Reboussin BA, Spangler J, Ross JC, Sutfin EL, *Tobacco Product Use and Mental Health Status Among Young Adults*, Addictive Behaviors (2018).

tobacco and other substances. Tobacco-naïve adolescents are more likely to initiate tobacco using e-cigarettes, and longitudinal prospective studies show that adolescents who use e-cigarettes are 3–4 times more likely to subsequently use combustible cigarettes.³² A nationally representative study in the US and a meta-analysis of studies showed that adolescents who use e-cigarettes are 3 times more likely to start smoking combustible cigarettes.³³

2. E-Cigarettes Like Puff Bar Cause Acute and Chronic Lung Injuries.

- 91. The use of e-cigarettes like Puff Bar cause significant lung toxicity and have been implicated in multiple severe pathological lung injuries.³⁴
- 92. Recent studies have demonstrated that exposure to e-cigarette flavored pods induces oxidative stress, inflammation, epithelial barrier dysfunction, and DNA damage in lung cells.³⁵
- 93. Lung epithelial cells are the first-line of defense and provide barrier protection from toxic inhalants. Epithelial barrier dysfunction can allow toxic inhalants access to systemic circulation by which they can interact with other tissues to generate fibrosis. In addition, the impaired barrier function allows greater passage of inhaled chemicals into the body, increasing inflammation both locally in the lungs and systemically. This can lead to acute and chronic lung

³² Berry KM, Fetterman JL, Benjamin EJ, et al., Association of Electronic Cigarette Use With Subsequent Initiation of Tobacco Cigarettes in US Youths, JAMA (2019); Soneji S, Barrington-Trimis JL, Wills TA, et al., Association Between Initial Use of E-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Young Adults: a Systematic Review and Meta-Analysis, JAMA PEDIATRICS (2017).

³³ Chaffee BW, Watkins SL, Glantz SA., *Electronic Cigarette Use and Progression from Experimentation to Established Smoking*, PEDIATRICS (Mar. 2018).

³⁴ Lauren F. Chun et al., *Pulmonary Toxicity of E-cigarettes*, 313 AM. J. PHYSIO. 193 (May 18, 2017), https://www.ncbi.nlm.nih.gov/pubmed/28522559.

³⁵ Thivanka Muthumalage, et al., *E-cigarette Flavored Pods Induce Inflammation, Epithelial Barrier Dysfunction, and DNA Damage in Lung Epithelial Cells and Monocytes*, 9 SCIENTIFIC REPORTS 19035 (2019), https://www.nature.com/articles/s41598-019-51643-6.

injury as well as exposure to, and increased susceptibility to, respiratory infections in users of ecigarettes.³⁶

- 94. Research has also demonstrated that ultrafine metal particles from heating devices have been found in e-cigarette aerosol, and in e-cigarette user's lungs.³⁷
- 95. In addition, exposure to e-cigarette aerosol has shown to significantly impair endothelial function comparable to impairment of endothelial function caused by use of combustible cigarettes.³⁸
- 96. It is well-established that endothelial dysfunction and injury from direct toxic effects of inhalants such as cigarette smoke, cause lung injuries such as COPD, emphysema, asthma and chronic bronchitis.³⁹
- 97. Recent epidemiological and toxicological studies detected links between asthma frequency and e-cigarette use in adolescents and reported that vaporized e-liquids containing the same flavor aldehydes found in Puff Bar induce inflammation in human respiratory epithelia.⁴⁰
- 98. A study published in December 2019, found that among individuals who never smoked combustible cigarettes, current e-cigarette use was associated with 75% higher odds of chronic bronchitis, emphysema, and COPD compared to those who never used e-cigarettes.⁴¹

³⁶ Laura E. Crotty Alexander et al. *Chronic Inhalation of E-cigarette Vapor Containing Nicotine Disrupts Airway Barrier Function and Induces Systemic Inflammation and Multiorgan Fibrosis in Mice*, 314 Am. J. PHYSIOL. 834 (2018), https://journals.physiology.org/doi/full/10.1152/ajpregu.00270.2017.

⁶⁶³ Pieter S. Hiemstra et al., *The Innate Immune Function of Airway Epithelial Cells in Inflammatory Lung Disease*, 45 Eur. Respir. J. 1150 (2015), https://erj.ersjournals.com/content/45/4/1150.

³⁷ Alessandra Caporale et al., *Acute Effects of Electronic Cigarette Aerosol Inhalation on Vascular Function Detected at Quantitative MRI*, 293 RADIOLOGY 97 (2019), https://www.ncbi.nlm.nih.gov/pubmed/31429679.

³⁸ Poonam Rao et al., *Juul and Combusted Cigarettes Comparably Impair Endothelial Function*, 6 TOBACCO REGUL. SCI. 30 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6953758/.

³⁹ Francesca Polverino et al. *COPD as an Endothelial Disorder: Endothelial Injury Linking Lesions in the Lungs and Other Organs?* 8 PULM. CIRC. 2045894018758528 (2018), https://www.ncbi.nlm.nih.gov/pubmed/29468936.

⁴⁰ Phillip W. Clapp and Ilona Jaspers, *Electronic Cigarettes: Their Constituents and Potential Links to Asthma*, 79 CURR ALLERGY ASTHMA REP. 17 (2017), https://www.ncbi.nlm.nih.gov/pubmed/28983782.

⁴¹ Albert D. Osei, et al., Association Between E-Cigarette Use and Chronic Obstructive Pulmonary Disease by Smoking Status: Behavioral Risk Factor Surveillance System 2016 and 2017, 132 Am. J. PREV. MED. 949 (2019), https://www.ncbi.nlm.nih.gov/pubmed/30853474.

- 99. Moreover, the flavoring compounds used in e-cigarettes, include numerous chemicals known to be toxins if inhaled, such as diacetyl, acetyl propionyl, and benzaldehyde. These chemicals are linked to serious lung disease. A multitude of published case reports have linked e-cigarette use to a variety of acute inhalational lung injuries such as lipoid pneumonia, bronchiolitis obliterans (popcorn lung), alveolar hemorrhage, eosinophilic pneumonia, hypersensitivity pneumonitis, chemical pneumonitis and collapsed lungs, among others.
- 100. Recent case reports have also linked spontaneous pneumothorax (lung collapse) to vaping and use of e-cigarettes.⁴³
- 101. The multiple pathological lung injuries and toxicity associated with e-cigarette use can lead to acute respiratory failure, intubation with mechanic ventilation and death.

3. E-Cigarettes Like Puff Bar Cause Cardiovascular Injuries.

102. In addition to severe lung injuries and addiction, e-cigarette products cause significant and severe risks of cardiovascular injuries. Studies have shown that use of e-cigarettes increase the risk of strokes and heart attacks.⁴⁴

⁴² Centers for Disease Control & Prevention, *Flavorings-Related Lung Disease* (Oct. 3, 2017), https://www.cdc.gov/niosh/topics/flavorings/default.html; Won Hee Lee *et al.*, *Modeling Cardiovascular Risks of E-Cigarettes with Human-Induced Pluripotent Stem Cell-Derived Endothelial Cells*. 73 J. Am. College of Cardiology 2722 (2019), https://www.ncbi.nlm.nih.gov/pubmed/31146818; Sheila Kaplan & Matt Richtel, *Mysterious Vaping Illness That's 'Becoming an Epidemic*,' N.Y. Times (Aug. 31, 2019), https://www.nytimes.com/2019/08/31/health/vaping-marijuana-ecigarettessickness.html?auth=login-email&login=email.

⁴³ Alex Bonilla et al., *Recurrent Spontaneous Pneumothoraces and Vaping in an 18-year-old Man: A Case Report and Review of the Literature*, 13 J. OF MED. CASE REPORTS 283 (2019), https://doi.org/10.1186/s13256-019-2215-4; Munish Sharma et al. *A Case Report of Secondary Spontaneous Pneumothorax Induced by Vape*, 11 Cureus e6067 (2019), https://doi:10.7759/cureus.6067.

⁴⁴ E-cigarettes linked to higher risk of stroke, heart attack, diseased arteries, American Stroke Association News Release, Abstract 9, Session A2 (Jan. 30, 2019), https://newsroom.heart.org/news/e-cigarettes-linked-to-higher-risk-of-stroke-heart-attackdiseased-arteries; Mohindar R. Vindhyal et al., *Impact on Cardiovascular Outcomes Among E-cigarette Users: A Review From National Health Interview Surveys,* 73 J. OF THE AM. COLLEGE OF CARDIOLOGY SUPPL. 2 (2019), www.onlinejacc.org/content/73/9_Supplement_2/11.; Paul M. Ndunda & Tabitha M. Muutu, *Electronic Cigarette Use is Associated with a Higher Risk of Stroke,* 50 Int'l Stroke Conference 2019 Oral Abstracts: Community/Risk Factors, Suppl. 1, Abst. 9, www.ahajournals.org/doi/10.1161/str.50.suppl_1.9.

- 103. Research has demonstrated that e-cigarettes significantly increase blood pressure and arterial stiffness, which also increases the risk of for strokes and heart attacks. ⁴⁵ Further, scientists have found that e-cigarettes cause oxidative stress, which leads to vascular disease and damage, known risk factors for cardiovascular injuries. ⁴⁶
- 104. Recent biological and epidemiologic studies found that significant associations exist between e-cigarette use and myocardial infarctions (heart attacks), which appear to be dose dependent. Biological investigations support this association, whereby a prothrombotic phenotype may develop after exposure to nicotine-containing e-cigarette vapors.⁴⁷

4. E-Cigarettes Like Puff Bar Cause and Contribute to Causing Seizures.

- 105. On April 3, 2019 the FDA Center for Tobacco Products issued a Special Announcement notifying the public of an increase in reports of tobacco-related seizures, specifically relating to an increase in e-cigarette use, particularly among youth.⁴⁸
- 106. The FDA is currently investigating the direct connection between e-cigarette use in young people and increased risk of seizures, and requested that physicians and members of the public report any similar incidents. *Id*.
- 107. Additionally, FDA Commissioner Scott Gottlieb, M.D. and the Principal Deputy Commissioner Amy Abernethy M.D., PhD issued a joint statement addressing the FDA's ongoing scientific investigation of seizures following e-cigarette use as a potential safety issue in youth and

⁴⁵ Charalambos Vlachopoulos et al., *Electronic Cigarette Smoking Increases Aortic Stiffness and Blood Pressure in Young Smokers*, 67 J. Am. Coll. Cardiol. (2016).

⁴⁶ Dennis Thompson, *Vaping May Hurt the Lining of Your Blood Vessels*, WebMD HealthDay Reporter (May 28, 2019), www.webmd.com/mental-health/addiction/news/20190528/vapingmay-hurt-the-lining-of-your-blood-vessels#1.

⁴⁷ Giuseppe Lippi & Emmanuel J. Favaloro, *An Update on Biological and Clinical Associations Between E-Cigarettes and Myocardial Infarction*, Semin. Thromb. Hemost. (2019), https://doi.10.1055/s-0039-3402451.

⁴⁸ Some E-cigarette Users Are Having Seizures, Most Reports Involving Youth and Young Adults, U.S. Food & Drug Administration (April 10, 2019), https://www.fda.gov/tobacco-products/ctp-newsroom/some-e-cigarette-users-are-having-seizures-most-reports-involvingyouth-and-young-adults.

young adults. The statement flags seizures following e-cigarette use as a source of concern for the FDA, adding that in addition to the 35 reported cases from 2010 to early 2019, the FDA "recognize[s] that not all of the cases may be reported" due to their voluntary nature.⁴⁹

- 108. Symptomatic nicotine toxicity is a consequence of excessive vaping.⁵⁰ As the FDA acknowledges in their statement, "seizures or convulsions are known potential side effects of nicotine poisoning."
- 109. It is well-documented that nicotine poisoning can cause seizures, including ingestion of e-cigarette fluid.⁵¹ Nicotine-induced seizure has long been considered a possible side effect of long-term nicotine exposure.⁵²

5. Animal Studies Demonstrate Carcinogenic Potential of E-Cigarettes.

- 110. In 2017, Canistro, et al. found that e-cigarettes induce toxicological effects that can raise the risk of cancer.⁵³
- 111. Similarly, a 2018 study measured the DNA damage induced by nitrosamines in the organs (lung, bladder, and heart) of mice subjected to e-cigarette vapor. They concluded that e-cigarette vapor induces DNA damage in all three organs and reduces DNA-repair functions and proteins in mouse lungs. They further found that nicotine-derived nitrosamine ketone can induce the same effects and enhance mutational susceptibility and tumorigenic transformation of cultured

⁴⁹ Scott Gottlieb & Amy Abernethy, Statement from FDA Commissioner Scott Gottlieb, M.D., and Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D., on FDA's Ongoing Scientific Investigation of Potential Safety Issue Related to Seizures Reported Following E-cigarette Use, Particularly in Youth and Young Adults (April 3, 2019), https://www.fda.gov/newsevents/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-principaldeputy-commissioner-amy-abernethy-md-phd.

⁵⁰ Adrienne Hughes et al., *An Epidemiologic and Clinical Description of E-cigarette Toxicity*, 57 CLIN. TOXICOL. 287 (2018), https://doi: 10.1080/15563650.2018.1510503.

⁵¹ Gerdinique C. Maessen et al., *Nicotine Intoxication by E-cigarette Liquids: A Study of Case Reports, Pathophysiology*, 58 CLINICAL TOXICOLOGY 1 (2020), https://www.tandfonline.com/doi/full/10.1080/15563650.2019.1636994.

⁵² Lucinda L. Miner et al., *The Effect of Chronic Nicotine Treatment on Nicotine-induced Seizures*, 52 PSYCHOPHARMACOLOGY 52 (2018), https://doi.org/10.1007/BF00212766.

⁵³ Donatella Canistro et al., *E-cigarettes Induce Toxicological Effects That Can Raise the Cancer Risk*, 7 Scientific Reports (2017).

human bronchial epithelial and urothelial cells (leading them to believe that vaping could contribute to heart disease and lung and bladder cancer in humans).⁵⁴

- 112. In 2019, Tang, et al. found that exposure to e-cigarette vapor, induced lung adenocarcinoma and bladder urothelial hyperplasia in mice.⁵⁵
- 113. It is evident that there is a potential association between e-cigarettes and cancer. Sadly, as time goes on, it is expected that the population of e-cigarette users will develop cancers caused and or contributed to by vaping a toxic stew of chemicals they inhaled. Long term epidemiological studies will likely reveal an increased risk of cancer among this generation of youth who were unwitting targets of companies like Puff Bar in complete and utter reckless disregard for their safety.

G. Defendants Knowingly Made False and Misleading Statements and Omissions Concerning Puff Bar's Nicotine Content.

- 114. Puff Bar's website represented that the "Original Puff Bar [is] equivalent to one pack of 20 cigarettes." This statement is deceptive, false and misleading.
- 115. Dr. Bonnie Halpern Felsher, a developmental psychologist at Stanford University, has conducted research that found that one Puff Bar has about 300 puffs and can contain about as much nicotine as *two or three packs of cigarettes*.⁵⁷
- 116. Puff Bar caused deceptive, false and misleading statements that its disposable ecigarette had an equivalent amount of nicotine as one pack of cigarettes to be distributed to

⁵⁴ Hyun-Wook Lee et al., *E-cigarette Smoke Damages DNA and Reduces Repair Activity in Mouse Heart, Lung, and Bladder as well as in Human Lung and Bladder Cells*, 115 PNAS E1560 (2018).

⁵⁵ Moon-shong Tang, et al., *Electronic-cigarette Smoke Induces Lung Adenocarcinoma and Bladder Urothelial Hyperplasia in Mice*, 116 PNAS 21727 (2019).

⁵⁶ Everything You Ever Wanted to Know About the Puff Bar Disposable Device, Puff Bar FAQ: What Is a Puff Bar, https://puffbar.com/blogs/vape-news/puff-bar-101-everything-you-ever-wanted-to-know-about-the-puff-bar-disposable-device (last visited June 25, 2020).

⁵⁷ Parents: Teens Are Still Vaping, Despite Flavor Ban. Here's What They're Using. https://www.npr.org/sections/health-shots/2020/02/17/805972087/teens-are-still-vaping-flavors-thanks-to-new-disposable-vape-pens (last visited June 26, 2020).

consumers including Plaintiffs. These Defendants have thus materially misrepresented the nicotine content of Puff Bar products to the consuming pubic including Plaintiffs.

- 117. Defendants also knew that the use of nicotine salts facilitates absorption of nicotine across biological membranes. Puff Bar's e-liquid formulation is highly addictive not only because it contains a high concentration of nicotine, but because it contains a particularly potent form of nicotine—i.e., nicotine salts.
- 118. Matt Myers of the Campaign for Tobacco Free Kids says, "Young people are inhaling more deeply and getting higher levels of nicotine in their lungs than they would have with a cigarette." *Id*.

CLASS REPRESENTATION ALLEGATIONS

119. Plaintiffs bring this class action against Defendants on behalf of themselves and all others similarly situated, as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure. The proposed classes are defined as follows:

All persons who purchased, in the United States, Puff Bar products;

All residents of New Jersey who purchased Puff Bar products;

All residents of New Jersey who, at the time of their use of Puff Bar products, were under the age of 18, and who procured and used Puff Bar products;

All legal guardians of United States residents who, at the time of their use of Puff Bar products, were under the age of 18, and who procured and used Puff Bar products; and

All legal guardians of New Jersey residents who, at the time of their use of Puff Bar products, were under the age of 18, and who procured and used Puff Bar products.

- 120. Plaintiffs reserve the right to propose subclasses or modify the above class definitions, based on the evidence adduced in discovery, or as necessary and appropriate.
- 121. This action has been brought and may properly be maintained as a class action against the Defendants pursuant to the provisions of Rule 23 of the Federal Rules of Civil

Procedure because there is a well-defined community of interest in the litigation and the proposed classes are ascertainable.

- 122. **Numerosity.** Plaintiffs do not know the exact size of the Classes, but they are each composed of more than 500 persons. The persons in the Classes are so numerous that joinder of all such persons is impracticable and the disposition of their claims in a class action rather than in individual actions will benefit the parties and the courts.
- 123. **Commonality.** There are questions of law or fact common to the Class or Classes that predominate over any questions affecting only individual members, including:
- a. Whether Defendants engaged in unlawful, unfair or deceptive business practices, as alleged herein;
- b. Whether Defendants made unlawful and misleading representations or material omissions with respect to Puff Bar products;
 - c. Whether Defendants unlawfully marketed Puff Bar to minors;
 - d. Whether Defendants have been unjustly enriched by their conduct;
- e. Whether Plaintiffs and class members are entitled to equitable and injunctive relief; and
 - f. Whether punitive damages should be awarded.
- 124. **Typicality.** Plaintiffs' claims are typical of the claims of the class. Plaintiffs and class members were injured through Defendants' substantially uniform misconduct. Plaintiffs are advancing the same claims and legal theories on behalf of themselves and class members, and there are no defenses that are unique to Plaintiffs' claims. Plaintiffs' and class members' claims are from the same set of operative facts and are based on the same legal theories.

- 125. **Adequacy.** Plaintiffs will fairly and adequately protect the interests of the class. Plaintiff has retained competent and capable attorneys experienced in complex and class action litigation, including consumer class actions. Plaintiffs and their counsel are committed to prosecuting this action vigorously on behalf of the class and have the financial resourced to do so. Neither Plaintiffs nor their counsel have interests that are contrary to or that conflict with the class.
- 126. **Predominance.** The common issues that comprise the basis for this lawsuit predominate over any individual issues. Adjudication of these common issues in a single action has important and desirable advantages of judicial economy.
- 127. **Superiority.** A class action is superior to other available methods for the fair and efficient adjudication of the controversy because, absent a class action, class members as a practical matter will be unable to obtain redress; Defendants' violations of their legal obligations will continue without remedy, additional consumers will be harmed, and Defendants will continue to retain ill-gotten gains; it would be a substantial hardship for most individual class members if they were forced to prosecute individual actions; once liability has been adjudicated, the Court will be able to determine the claims of all class members; a class action will permit an orderly and expeditious administration of the claims, foster economies of time, effort and expense, and ensure uniformity of decisions; the lawsuit presents no difficulties that would impede its management by the Court as a class action; and Defendants acted on grounds generally applicable to class members, making class-wide relief appropriate.

CAUSES OF ACTION

FIRST CAUSE OF ACTION⁵⁸ Violation of the New Jersey Product Liability Act N.J. STAT. ANN. 2A:58C-1 et seq.

- 128. Plaintiffs incorporate by reference paragraphs 1–127 above as if fully set forth herein and further declare:
- 129. Defendants designed, engineered, developed, manufactured, fabricated, assembled, equipped, tested or failed to test, inspected or failed to inspect, labeled, advertised, promoted, marketed, supplied, distributed, wholesaled, and sold the Puff Bar devices, which were intended to be used as a method of ingesting nicotine and the other aerosolized constituents of Puff Bar's eliquid solution.
- 130. Defendants knew or, by the exercise of reasonable care, should have known that Puff Bar's products under ordinary use were harmful or injurious, particularly to youths and adolescents, including the high delivery of nicotine, the inclusion of a multitude of other harmful ingredients, the likelihood of nicotine addiction and the risks of lung injuries, seizure, strokes, heart attacks, cardiovascular injuries, behavioral, cognitive and mental health injuries, among other harmful effects.

The Tobacco Control Act's preemption provision, 21 U.S.C. § 387, does not apply to the Defendants' advertisements and mislabeling as described herein. The Tobacco Control Act contains a subsection titled "EXCEPTION" which states: "[The preemption clause] does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products." 21 U.S.C.A. § 387p(2)(B). Thus, the exception clause expressly excepts advertisements from preemption and no aspect of Plaintiffs' claims based on allegedly misleading or fraudulent advertising is preempted by the Tobacco Control Act. The Tobacco Control Act further preserves to the States the ability to "enact, adopt, promulgate, and enforce any law...with respect to tobacco products that is in addition to, or more stringent than, requirements established under this chapter, including a law...or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products....The Tobacco Control Act also has a "Rule of Construction Regarding Product Liability," which provides: "No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State."

- 131. As described in this complaint, Defendants designed and marketed their products to appeal to nonsmokers, youths and adolescents and to encourage them to buy and use the product.
- 132. As the manufacturers/sellers of a product, Defendants have the duty to make/sell a product that is reasonably safe—i.e., reasonably fit, suitable and safe for its intended or reasonably foreseeable uses.
- 133. Defendants owe this duty to direct users of the product, to reasonably foreseeable users of the product, and to those who may reasonably be expected to come into contact with it.
- 134. Puff Bar products are not reasonably safe for their intended purpose because of a design defect as well as the failure to adequately warn and/or instruct.

A. Design Defect

- 135. Puff Bar products are defectively designed because they do not perform as safely as a reasonable and ordinary consumer would reasonably assume and reasonably expect.
- 136. Puff Bar products contain and deliver more nicotine than is represented, are delivered by heat vaporization inhaled into the body, and contain and deliver other harmful products that injure multiple organ systems and are designed to cause nicotine addiction.
- 137. The risks inherent in the design of Puff Bar products significantly outweigh any benefits of such design.
- 138. At all relevant times, Defendants could have utilized cost effective, reasonably feasible alternative designs to minimize these harms, such as by designing products that delivered less nicotine per puff, used less potent and addictive forms of nicotine (without reduction of the "throat hit"), reduced repeated exposure to toxic chemicals that do not pose substantial health risks to users while still delivering sufficient levels of nicotine to preexisting cigarette smokers.

- 139. At all relevant times, Defendants could have designed the products in a way in which they would not be as appealing to minors and non-smokers by designing the device with a throat hit and only designing non-flavored e-liquids.
- 140. Puff Bar is unreasonably dangerous and therefore defective in design because it is made to create and sustain addiction and are more addictive than necessary compared to other electronic cigarettes and combustible cigarettes, and the body is absorbing nicotine at higher levels than other electronic cigarettes and combustible cigarettes as the amount of nicotine contained in Puff Bar products is as much as two to three times as high as that in a pack of cigarettes, and not the equivalent of one pack of cigarettes, as represented.
- 141. Puff Bar products were defective and unreasonably dangerous when they left the Defendants' possession and control. The defects continued to exist through the products' sale to and use by consumers, including Plaintiffs and the Class, who used the products without any substantial change in the products' condition.
 - 142. Plaintiffs, and those similarly situated, were direct and foreseeable users.
- 143. Plaintiffs, and those similarly situated, used Puff Bar products as intended or in reasonably foreseeable ways.
- 144. At all relevant times, Plaintiffs and the Class were unaware of the design defects described in the complaint. Defendants knew or had reason to know that youths and adolescents would not fully realize the dangerous and addictive nature of the Puff Bar products and the long-term complications nicotine addiction can present, or that, due to their youth, inexperience and/or immaturity of judgment, would recklessly disregard such risks.
- 145. The defect(s) in the design of Defendants' products as described herein were a direct and proximate cause of Plaintiffs' injuries. Plaintiffs have in the past and will continue to

suffer from bodily injury; pain and suffering; disability; disfigurement; loss of the capacity for the enjoyment of life; aggravation of pre-existing conditions; medical and hospital care and expenses; rehabilitation expenses; and severe emotional distress.

B. Failure to Warn/Instruct

- 146. Puff Bars are marketed to youth, made accessible to youth, and have inadequate nicotine warnings.
- 147. Puff Bar products are sold in a defective condition that is unreasonably dangerous and unsafe to the consumer because the Defendants failed to adequately warn about the risk of nicotine addiction and entirely failed to warn of the risks of lung injuries, seizure, strokes, heart attacks, cardiovascular injuries, behavioral, cognitive and mental health injuries, among other harmful effects, as described herein.
- 148. The Defendants, as the manufacturer/seller of a product had a duty to provide adequate warnings and/or instructions about the dangers that Puff Bar products may present.
- 149. Defendants were aware that Puff Bar products posed risks that were known and knowable in light of scientific and medical knowledge that was generally accepted in the scientific community at the time of design, manufacture, distribution, and sale of Puff Bar devices.
- 150. Puff Bar products are defective because, among other reasons, Defendants failed to adequately warn or instruct foreseeable users, including youth and adolescent users, that:
 - a. The amount of nicotine contained in Puff Bar products is as much as two to three times as high as that in a pack of cigarettes, and not the equivalent of one pack of cigarettes, as represented;

- b. That Puff Bar products cause, maintain, or aggravate nicotine addiction and subject consumers to the risks of concomitant health hazards that addictive, *i.e.*, compulsive behavior can result in, and that this danger was even greater for minors;
- c. That Puff Bar products cause harm by increased exposure to nicotine and other harmful, toxic ingredients as described herein;
- d. That Puff Bar is an e-cigarette not intended for persons under the age of 26;
- e. That Puff Bar delivered more nicotine than cigarettes;
- f. That Puff Bar's pharmacokinetic profile had been engineered to create risks of abuse and addiction that exceeded that of a cigarette; and
- g. That Puff Bar can be life-threatening and carries the risk of lung injuries, seizure, strokes, heart attacks and cardiovascular injuries, behavioral, cognitive and mental health injuries among other harmful effects.
- 151. Instead, as described herein, Defendants marketed their products to minors and made them available in a wide variety of youth-friendly colors and flavors.
- 152. The defects in Puff Bar products, including the lack of warnings, existed at the time the Puff Bar devices were sold and/or when the Puff Bar devices left Puff Bar's possession or control.
- 153. Ordinary consumers would not have recognized the potential risks of Puff Bar products when used in a manner reasonably foreseeable to Defendants. The Puff Bar devices were expected to be used by Plaintiffs and the Class without substantial change in their condition from the time of their manufacture or sale.
- 154. Plaintiffs, and those similarly situated, were direct and reasonably foreseeable users.

- 155. At all times relevant, Plaintiffs and members of the Class were not aware of and would not have recognized the risks of using a Puff Bar device because Defendants intentionally downplayed, misrepresented, concealed, and failed to warn of the heightened risks of nicotine exposure and addiction.
- 156. The failure of the Defendants to adequately warn about its defective products and disseminate misleading advertisements through conventional and social media avenues created a danger of injuries described herein that were reasonably foreseeable at the time of labeling, design, manufacture, distribution, and sale of Puff Bar devices.
- 157. The inadequate warning(s) as described herein were a direct and proximate cause of Plaintiffs' injuries. Plaintiffs, and those similarly situated, have in the past and will continue to suffer from bodily injury; pain and suffering; disability; disfigurement; loss of the capacity for the enjoyment of life; aggravation of pre-existing conditions; medical and hospital care and expenses; rehabilitation expenses; and severe emotional distress.
- 158. Pursuant to the New Jersey Product Liability Act, Plaintiffs assert all claims and causes of action against the Defendants, including but not limited to negligence, breach of implied warranty of merchantability, breach of implied warranty of fitness, strict liability, failure to warn and/or inadequate warning on theories of both negligence and strict liability, all claims and causes of action pertaining to the design, manufacture, sale and distribution of Defendants' defective ecigarette products which were not reasonably fit, suitable or safe for their intended purpose as they were defectively designed and failed to contain adequate warnings and/or instructions.

SECOND CAUSE OF ACTION Preliminary and Permanent Injunction

159. Plaintiffs incorporate by reference paragraphs 1–127 above as if fully set forth herein and further declare:

- 160. Despite being on the market illegally, Puff Bars are still being sold on various e-commerce websites, including eliquidstop.com—a site owned by Defendants, Nick Minas and Patrick Beltran.
- 161. Defendants' actions—designing, marketing, and selling Puff Bar in ways that it knows will attract minors and deceptively downplaying the potency and danger of the nicotine in Puff Bar—constitute unlawful acts under New Jersey Law.
- 162. Nicotine addiction constitutes irreparable harm. Nicotine is a neurotoxin, which means that it is poisonous to the human brain. Further, the brains of teenagers are particularly vulnerable to nicotine's neurotoxic effects. Nicotine causes macromolecular alterations of the brain.
- 163. Moreover, Puff Bars came onto the market in 2019—well after the FDA's Deeming Rule took effect on August 8, 2016—without first undergoing premarket review and receiving market authorization. As a result, Puff Bars are illegally on the market.
- 164. Based on the factual allegations above, Plaintiffs and those similarly situated established a clear legal right, an inadequate remedy at law and that irreparable harm will arise absent injunctive relief.
- 165. Thus, Defendants, officers, directors, employees, agents, and all those acting in concert with them, should be preliminarily and permanently enjoyed from:
- a. Offering, selling, delivering, or in any manner, providing or facilitating others to provide Puff Bar products to minors within this State;
- b. Offering, selling, delivering, or in any manner, providing or facilitating others to provide any flavors other than tobacco through online sales;

- c. Engaging or participating in any marketing or advertising activities within this State that are intended or are known to likely appeal to minors, and should thus be enjoined from: sending marketing emails to minors within this State; advertising outdoors within 1,000 feet of schools and playgrounds within this State; sponsor any sporting, entertainment, or charity event in this State; providing free or discounted samples, starter kits or e-cigarette products to consumers, including being enjoyed from providing automatic renewals or bulk orders; advertising in any fashion in media or outlets that serve consumers under 30 years;
- d. Offering, selling, delivering, or in any manner, providing or facilitating others to provide Puff Bar products within this State unless and until Puff Bar obtains Premarket Approval or approved as a Modified Risk Tobacco Product under the Tobacco Control Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

- A. An order certifying the proposed classes, designating Plaintiffs as the named representatives of the classes, and designating the undersigned class counsel;
- B. An order enjoining Defendants from further negligent, deceptive, unfair, and unlawful conduct as alleged herein;
- C. Awarding actual, compensatory, and consequential damages;
- D. Awarding other monetary and equitable relief for diagnostic testing, medical monitoring, and nicotine cessation programs;
- E. Awarding restitution;
- F. Awarding reasonable attorneys' fees, and costs of this case;
- G. Awarding prejudgment and post-judgment interest;
- H. Such other and further relief as the Court deems appropriate under the circumstances.

JURY TRIAL DEMAND

Plaintiffs hereby demand a jury trial on all issues so triable.

Dated: September 25, 2020 Respectfully submitted,

By: /s/Jeffrey L. Haberman__

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